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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,098	06/20/2001	Robert Stuart Coffin	117-340	7947

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EXAMINER

LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/29/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/762,098

Applicant(s)

COFFIN ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3--5, 7-10 and 27-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3--5, 7-10 and 27-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 1, 3-5, 7-10 and 27-58 are pending.

#### ***Response to Amendment***

This is a response to the amendment, paper No. 8, filed 05/06/03. Claims 1, 3, 7-10, and 27 have been amended. New claims 28-58 are added. Claims 1, 3-5, 7-10 and 27-58 are pending before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

#### ***Petition***

Applicant's petition under the Rule 181 filed 08/16/2002 is DISMISSED because the petition, as filed, was premature.

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 5 and 7 are still rejected under 35 U.S.C. 102(b) as being anticipated by Moriuchi et al. (J. Virol. 1993, Vol. 67, pp. 2739-2746) on the same ground as stated in the previous Office Action.

3. Applicants traverse the rejection and argue that claim 1 is directed to a process for preparing a pharmaceutical composition comprising the step of formulating the mutant HSV with a pharmaceutically acceptable carrier and diluent. This step is not taught or suggested by Moriuchi et al.

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4. Applicant's arguments has been respectfully considered; however, it is not found persuasive because Moriuchi et al. explicitly teach the method for using VZV ORF10 to rescue the VP16 mutant HSV virus, in which the VZV ORF 10 is expressed under an inducible promoter (human metallothionein) in a cell line that is used to enhance the HSV virion production. Moriuchi et al. also teach steps of harvesting and purifying the mVP16 mutated virus (See lines 9 on 1<sup>st</sup> col. through lines 6 on 2<sup>nd</sup> col. of page 2744). Regarding to the limitation of a pharmaceutical acceptable carrier or diluent, the isolated HSV disclosed by Moriuchi et al. must be inherently contained in pharmaceutical receptacle carrier or diluent because the viruses isolated by Moriuchi et al. has to be in a non-harmful solution for determine the viral production titer or infectivity (See lines 1-6 on 2<sup>nd</sup> col. of page 2744). Therefore, the rejection on claims 1, 5 and 7 are maintained.

#### 5. New Ground of Rejection

##### *Claim Rejections - 35 USC § 103*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 3-5, 7-10, 27 and 28-58 are rejected under 35 U.S.C. 103(a) as being obvious over Speck et al. (WO 96/04395A1), Moriuchi et al. (J. Virol. 1993, Vol. 67, pp. 2739-2746) and Purewall et al. (Virology 1994, Vol. 198, pp. 385-389).

8. Claimed invention is drawn to the method for producing a VP16 mutated HSV or a vector of HSV having VP16 gene mutation, wherein the VP16 mutation is trans-complemented by a functional equivalent of a non-HSV VP16 polypeptide, preferably this gene is the equine herpes virus 1 gene 12 or bovine herpes virus BTIF that is carried by an plasmid and expressed in the cell line used for propagating the VP16 mutated HSV. The said vector further comprises

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other essential gene deletion, such as ICP4 and /or ICP27 that trans-complemented by an equivalent of ICP4 or ICP27 of another herpesvirus driven by MMTV LTR promoter.

9. Speck et al. teach a mutated herpesvirus including HSV-1, HSV-2 etc. and a method of making and using the mutant as a recombinant virus vector, wherein the mutation is to impair the VP16 gene or the gene encoding ICP0, ICP4, ICP27 etc. The vector made by the mutated herpesvirus further comprises a DNA insert encoding a heterologous polypeptide. Speck et al. also teach that the mutated viruses and vectors can be formulated as pharmaceutical formulation in any of the way conventionally used for the formulation of live virus vaccines (See lines 6-8 on page 15 and claims 1-15). Speck et al. do not teach to trans-complement the mutated VP16 with a functional equivalent of VP16 gene, preferably the EHV gene 12 or BHV BTIF.

10. Moriuchi et al. explicitly teach the method for using VZV ORF10 to rescue the VP16 mutant HSV virus, in which the VZV ORF 10 is expressed under an inducible promoter control (human metallothionein) in a cell line that is used to enhance the HSV virion production. Moriuchi et al. also teach a step of harvesting and purifying the mVP16 mutated virus (See lines 9 on 1<sup>st</sup> col. through lines 6 on 2<sup>nd</sup> col. of page 2744). Moriuchi et al. do not teach to use EHV gene 12 or BHV BTIF to trans-complement the mutated VP16.

11. Purewall et al. teach that like VP16 counterpart in VZV, EHV-1 and EHV-4 counterparts of VP16 strongly transactivate HSV-1 IE gene (See lines 11-32 on 2<sup>nd</sup> col. of page 387).

12. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was filled to be motivated by the cited references to propagating a VP16 and ICP4 or ICP27 double mutated HSV in a cell line transfected to express EHV-1 gene 12 with a highly expected success because the VP16 and ICP4 double mutated virus as disclosed by Speck is able to grow well in a cell line that is able to trans complement the defective function of ICP4 and/or ICP27, an additional trans complement of defective VP16 with HSV Vp16 homology such as VZV ORF10 or EHV-1 gene 12 would be able to provide a better condition for propagating this double mutated HSV-1 as . Since the claimed invention has not been found as an unexpected result, the claimed invention as a whole is still prima facie obvious absence unexpected results.


### ***Conclusion***

No claims are allowed.

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13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
14. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 05/-6/2003 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
15. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.
17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.
18. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li  
July 21, 2003

  
JAMES HOUSEL 7/28/03  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600